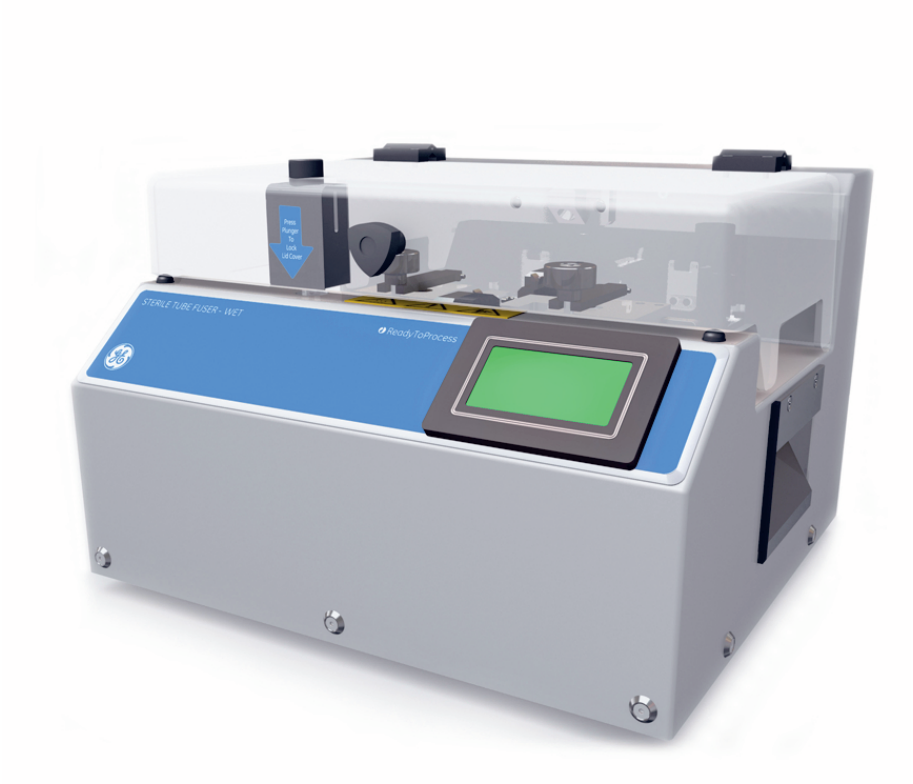
GE Healthcare
Life Sciences

STERILE TUBE FUSER - WET

User Manual



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1 Introduction

Purpose of the User Manual

The User Manual provides you with the instructions needed to operate STERILE TUBE FUSER - WET.

Prerequisites

You must read *STERILE TUBE FUSER - WET Operating Instructions*.

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1.1 Important user information

Read this before using STERILE TUBE FUSER - WET

All users must read the entire *STERILE TUBE FUSER - WET Operating Instructions* before installing, using or maintaining the instrument. Always keep the *Operating Instructions* at hand when using STERILE TUBE FUSER - WET.

Do not operate STERILE TUBE FUSER - WET in any other way than described in the user documentation. If you do, you may be exposed to hazards that can lead to personal injury and you may cause damage to the equipment.

Intended use

STERILE TUBE FUSER - WET is an automated instrument designed to produce sterile joints of thermoplastic tubings.

STERILE TUBE FUSER - WET shall not be used in any clinical procedures, or for diagnostic purposes.

Safety notices

This user documentation contains WARNINGS, CAUTIONS and NOTICES concerning the safe use of the product. See definitions below.

Warnings

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

Cautions

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

Notices

NOTICE

NOTICE indicates instructions that must be followed to avoid damage to the product or other equipment.

Notes and tips

Note: *A Note is used to indicate information that is important for trouble-free and optimal use of the product.*

Tip: *A tip contains useful information that can improve or optimize your procedures.*

Typographical conventions

Software items are identified in the text by ***bold italic*** text. A colon separates menu levels, thus ***File:Open*** refers to the ***Open*** command in the ***File*** menu. Hardware items are identified in the text by **bold** text (e.g., **Power** switch).

1.2 Regulatory information

Introduction

This section lists the directives and standards that are fulfilled by STERILE TUBE FUSER - WET.

Manufacturing information

The table below summarizes the required manufacturing information. For further information, see the EC Declaration of Conformity document.

Requirement	Content
Name and address of manufacturer	GE Healthcare Bio-Sciences AB, Björkgatan 30, SE 751 84 Uppsala, Sweden

CE Conformity

Directive	Title
2006/42/EC	Machinery Directive (MD)
2006/95/EC	Low Voltage Directive (LVD)
2004/108/EC	ElectroMagnetic Compatibility (EMC) Directive

International standards

Standard	Description	Notes
EN 61010-1 IEC 61010-1 UL 61010-1 CAN/CSA-C22.2 No.61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use	EN standard is harmonized with EU directive 2006/95/EC

Standard	Description	Notes
EN 61326-1 IEC 61326-1 (Emission according to CISPR 11, Group 1, class A)	Electrical equipment for measurement, control and laboratory use - EMC requirements	EN standard is harmonized with EU directive 2004/108/EC
EN ISO 12100	Safety of machinery. General principles for design. Risk assessment and risk reduction.	EN ISO standard is harmonized with EU directive 2006/42/EC

CE marking

CE

The CE marking and the corresponding Declaration of Conformity is valid for the instrument when it is:

- used as a stand-alone unit, or
- connected to other CE-marked instruments, or
- connected to other products recommended or described in the user documentation, and
- used in the same state as it was delivered from GE Healthcare, except for alterations described in the user documentation or explicitly authorized by GE Healthcare.

Regulatory compliance of connected equipment

Any equipment connected to STERILE TUBE FUSER - WET should meet the safety requirements of EN 61010-1/IEC 61010-1 or relevant harmonized standards. Within the European Union, connected equipment must be CE-marked.

1.3 STERILE TUBE FUSER - WET

Introduction

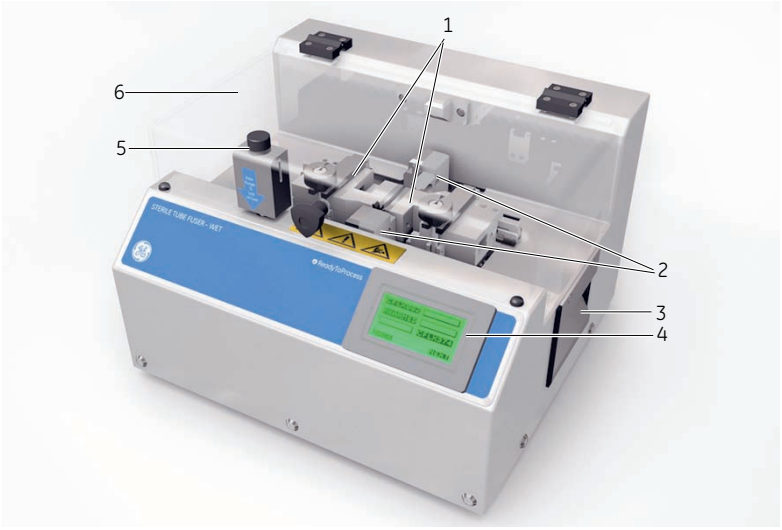
STERILE TUBE FUSER - WET is an automated instrument designed to produce sterile joints of thermoplastic tubings without the need for a laminar flow cabinet or similar environmental control unit. It is useful for connecting tubing between process containers and equipment. The unit is designed to connect large diameter liquid filled tubing, enabling high flow rates and large transfer volumes.

Major uses are in bioprocessing and in aseptic pharmaceutical applications.

STERILE TUBE FUSER - WET is equipped with an embedded software for control and supervision.

Main parts

The illustration below shows the main parts of STERILE TUBE FUSER - WET.

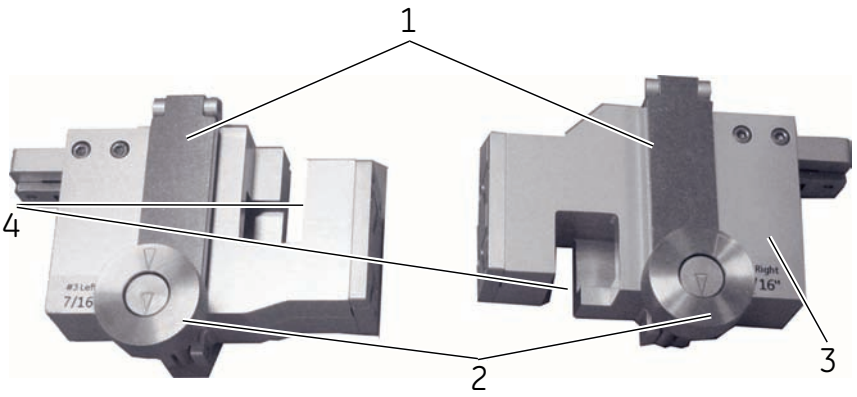


Part	Description
1	Tubing holders
2	Blade holders
3	Lifting handle
4	Touch screen

Part	Description
5	Cover Lock button
6	Cover or Lid

Tubing holders

The illustration below shows the holders used in STERILE TUBE FUSER - WET instrument.



Part	Function
1	Top handle
2	Knob
3	Upper holder body
4	Place for inserting external clamps

Clamp

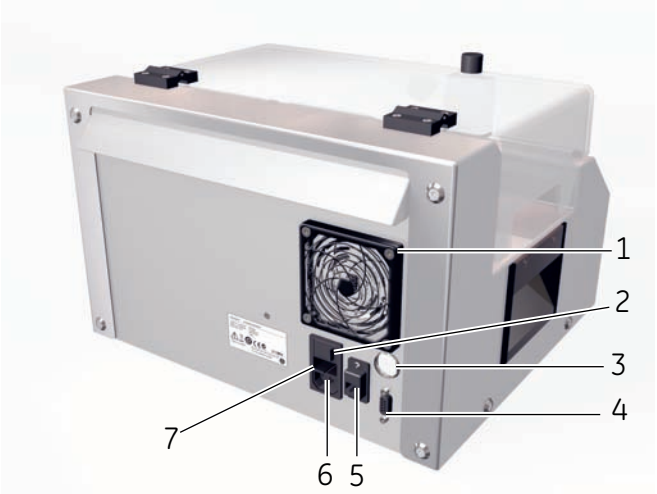
The illustration below shows the clamp used with the holders on STERILE TUBE FUSER - WET.

PTFE coated cutting blades

The illustration below shows the blade used in STERILE TUBE FUSER - WET instrument.

Rear panel

The illustration below shows the rear panel of STERILE TUBE FUSER - WET.



Part	Function
1	Ventilation fan
2	Power switch
3	Key lock
4	Printer connector
5	Data connector
6	Power connector
7	Fuse holder

1.4 Disclaimer

STERILE TUBE FUSER - WET has been tested to produce welds of sufficient quality and strength to permit sterile transfers. Under no circumstances can data in this manual be submitted to any regulatory agency in support of a clinical product without specific written permission from the manufacturer.

The manufacturer guarantees the mechanical operation of the equipment only and is not liable for any loss incurred due to the use of this equipment. Equipment must be maintained and serviced as per the recommended schedule to ensure warranty coverage.

It is the responsibility of the end user to verify and validate the suitability of this instrument for a specific application.

2 Operation

Precaution

WARNING

The end user must ensure that all installation, maintenance, operation and inspection is carried out by qualified personnel who are adequately trained, understand and adhere to local regulations and the operating instructions, and have a thorough knowledge of the entire system and process.

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2.1 Introduction

Operation overview

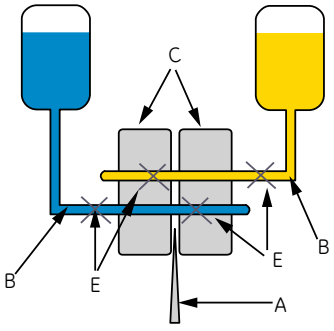
STERILE TUBE FUSER - WET is used to weld together thermoplastic tubing in a sterile manner. Each piece of tubing is connected on one end to a container, bag or process equipment. The other end is sealed by a clamp, plug, or other closure.

See *Section 4.2 Compatible tubing , on page 43* for all approved tubing types filled with fluids like media, buffers, etc. It is not possible to fuse non-thermoplastic materials such as PTFE or silicone.

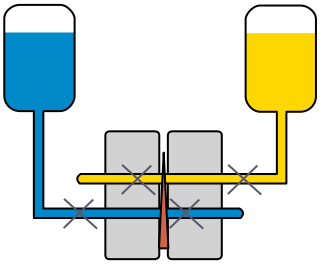
Schematic operation

The table below describes a typical workflow for tube welding with STERILE TUBE FUSER - WET. Each weld cycle takes about 3 minutes.

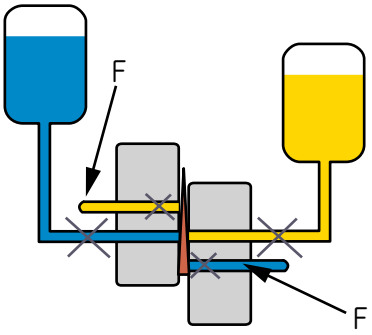
Stage	Description
1	The cutting blade (A) is installed. It retracts into the instrument.
2	The tubing (B) is placed in the holders (C). (B) indicates the part of tubing to be connected. (E) indicates the external tubing clamps that can be used to avoid large amount of liquid spillage in case of poor weld or weld failure.



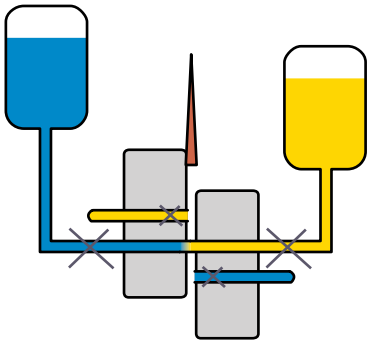
Stage	Description
3	The cutting blade heats up and when heated it cuts through both tubing pieces. The cut ends are held against the hot blade.



4	The tubing holders slide the cut tubing into alignment. The hot cutting blade is held against the cut tubing to ensure sterility. (F) indicates the part of the tube to be discarded.



5	The blade moves up and the tubing ends are fused together to form a welded connection.



Stage	Description
6	The connected tubing is removed and the used cutting blade and cut tubing ends are discarded.

Prior to use

Prior to use, the instrument should be tested by making a few trial welds, which should be examined. If the sample welds are not acceptable, contact Service.

Safety precautions

WARNING

Hot surfaces of STERILE TUBE FUSER - WET. The cutting blade reaches 400°C during the heating cycle. Do not try to open the protective cover during the welding.

WARNING

Pinch hazard when using STERILE TUBE FUSER - WET. There are movable parts under the protective cover. Do not try to open the protective cover during the welding.

WARNING

In case of power failure and instrument reset, STERILE TUBE FUSER - WET unlocks the Cover Lock.

- Do not touch the blade for approximately one minute till it cools down.
- If there is liquid spillage due to poor weld or no weld, clean the spillage using proper cleaning agent depending on the hazard level of the process chemicals/biologicals being used and continue with tube welding process.

WARNING

Use external tubing clamps on both tubes to avoid electrical shock hazard due to large amount of liquid spillage and contamination of the complete process batch in case of poor weld or weld failure.

WARNING

Visually inspect the weld joint before unlocking the tube holders. In case of poor weld, no weld or liquid spillage inside the instrument, switch off the instrument before attempting to remove the tubes.

WARNING

Remove the external clamps only after confirming a good weld.

CAUTION

Use only tubing that is compatible with the instruments.

NOTICE

Carefully inspect connections before use.

NOTICE

Cover must be closed for the instrument to operate. The cover interlock will only allow it to be opened when it is safe. The Cover Lock button pops out to indicate that the cover is released and can be opened.

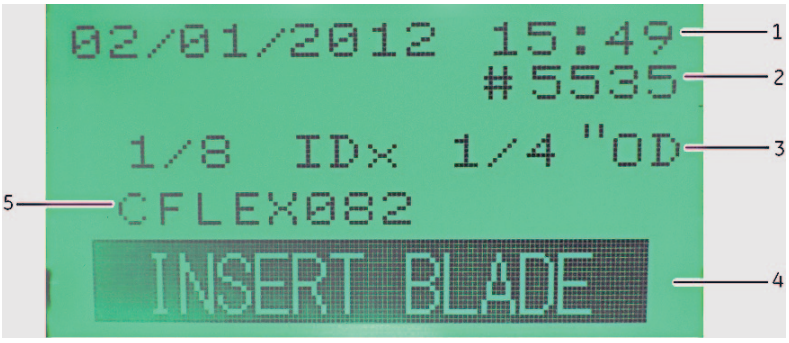
Reproducible procedure

STERILE TUBE FUSER - WET is a fully automated instrument. It indicates the successful completion of the welding cycle if all operations have functioned properly. The procedure can be completely reproduced. The risk for any potential cross contamination is reduced when a new disposable blade is used for each cycle.

Controls

During normal operation, the Cover Lock button ensures that the cover is locked while STERILE TUBE FUSER - WET is operating and also initiates the pre-programmed sequence. The Cover Lock button pops out to indicate that the cover is released and can be opened.

The touch panel display provides the operator interface for user actions and data entry.



Part	Function
1	Date and time
2	Unit ID number
3	Tubing size
4	Message area to display required user action
5	Tubing type

The main power switch is located at the rear of the unit. A key lock on the rear is used with the programming key for diagnostics and program downloads. A programming lock key is normally supplied with the unit but it is also included with a PC interface program and data cable kit from GE Healthcare.

Date and time edit option

The user can change the date and time on the STERILE TUBE FUSER - WET instrument. To change the date and time, follow the steps below.

Step	Action
1	Power up the instrument.
2	Follow the usual tube welding procedure until the ***INSERT BLADE*** screen is displayed. Do not insert the blade.
3	Insert the programming key in the key lock in the rear panel of the instrument and turn it to the horizontal position. Refer to *Rear panel, on page 13*. *Result*: The ***INSERT BLADE*** screen displays ***SETUP*** and ***EDIT*** options when the programming key is detected.
4	Select the ***SETUP*** option on the display.
5	Navigate to the ***DATE AND TIME*** screen by selecting it on the display.

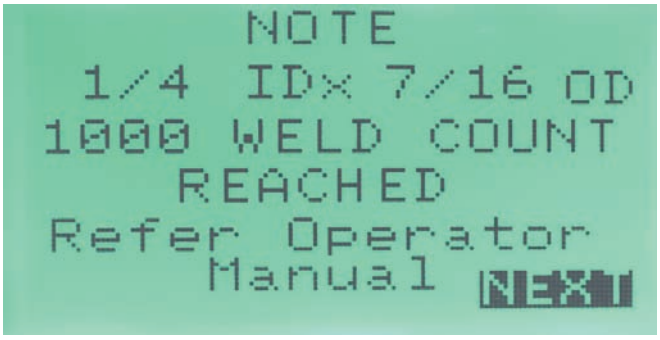
Step	Action
6	Select the required fields and edit the date and time values with the help of the touch keypad. Select the ***SET*** and ***DONE*** fields to save the updates. *Result*: The ***INSERT BLADE*** screen displays the updated date and time.
7	Turn the programming key back to the vertical position to continue with the tube welding process.

Tube holder weld count tracker

You can keep track of the number of tube welds performed on a set of tube holders.

Note: *The recommended maximum number of welds that should be performed using a set of tube holders is 1000 weld counts.*

The following message is displayed once the weld count on a particular set of tube holder reaches 1000.



After 1000 weld counts, you must verify the quality of the tube weld joints at regular intervals. The recommended maximum interval is 500 weld counts.

To verify the weld quality, perform the following tests on at least three weld samples that are fluid- filled and sealed at both ends.

Step	Action
1	Perform all the tests mentioned in *Inspecting weld quality, on page 35*.
2	Subject the welded sample tubes to a tensile load as listed below, and ensure that the weld joints do not show any leakage. • 1.5 kg for C-Flex 082 1/8" × 1/4" (ID x OD) tubing. • 2.5 kg for C-Flex 082 1/4" × 7/16" (ID x OD) tubing.
3	Subject the welded sample tubes to a flow test. The weld joint shall not restrict flow by more than 25%.

If the test results of all the samples meet the acceptance criteria and if you wish to continue using the same set of tube holders, follow the steps below.

Step	Action
1	Select the ***NEXT*** option from the display screen. Refer to the image above. *Result:* The ***INSERT BLADE*** message is displayed. ***Note:*** *The instrument displays the **NOTE** message for every new weld cycle after 1000 weld counts, until the tube holder is replaced. This message helps the user to keep track of the weld counts to verify the weld quality at regular intervals.*
2	Continue with the normal welding procedure. To do so, follow the steps from *Insert a cutting blade, on page 27*.

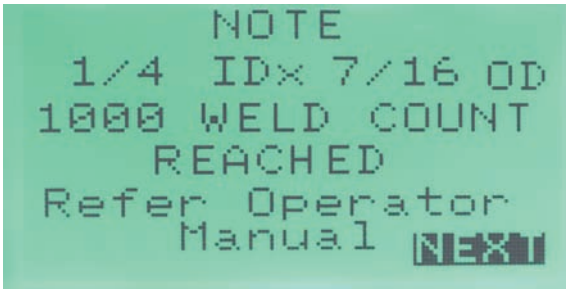
If the test results of all the samples fail to meet the acceptance criteria, replace the tube holders. Contact Service for assistance.

Once the tube holders are replaced, follow the steps below to reset the weld count.

NOTICE

The ***RESET HOLDER COUNT*** option should only be used when the old set of tube holders is replaced with a new set of tube holders. Do not use this option when the same set of the old tube holders is used after 1000 weld counts.

Step	Action
1	Power up the instrument.
2	Follow the usual tube welding procedure. The screen below is displayed if the weld count is 1000 or more.



Step	Action
3	Select the ***NEXT*** option from the display. *Result:* The ***INSERT BLADE*** screen is displayed. Do not insert the blade.
4	Insert the programming key in the key lock and turn the key to the horizontal position. *Result:* The following screen with the ***SETUP*** details is displayed.

5	Select the ***SETUP*** option from the display. *Result:* The ***RESET HOLDER COUNT*** screen is displayed.

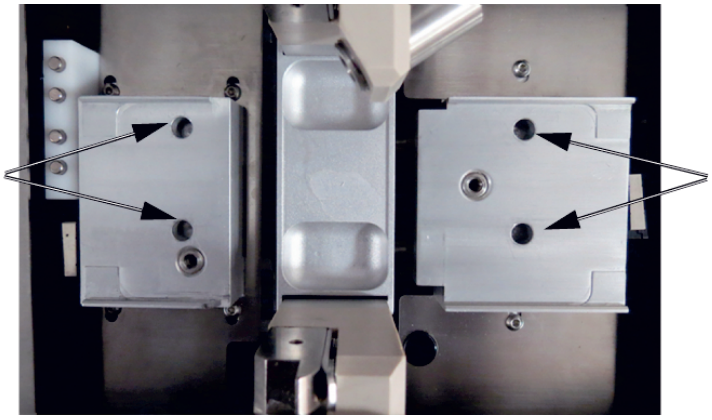
6	Select the ***RESET*** option to reset the weld count to zero.
7	Select the ***DONE*** option to save the changes.
8	Turn the programming key to the vertical position and continue with the tube welding procedure.

2.2 Instructions for fusing tubes

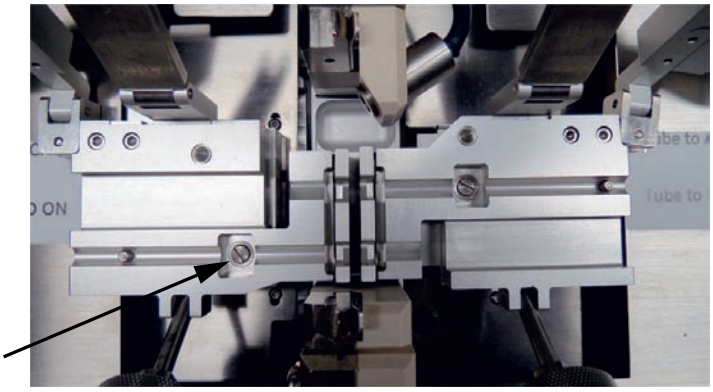
Start the instrument and install the tubing holders

Step	Action
1	Switch on the power to STERILE TUBE FUSER - WET by pressing the power switch to the "**I**" position. Before powering on ensure that • The tubes are not inserted in the holders. • The Programming Lock key is not in diagnostics mode (horizontal position). *Result:* The display screen shows the software intializing and prompts the user to close the cover of the STERILE TUBE FUSER - WET instrument.
2	Press and hold the Cover Lock button for a few seconds until you hear a click. Close the cover. The instrument proceeds with initialization and all the motors (X, Y and Z axis) move to their respective home positions. *Result:* The display shows the ***NO TUBE HOLDER INSTALL HOLDER*** screen.
3	Open the cover to install the holders on the left and right side. ***Note:*** *Both the left and right tube holders should be of the same size.* The supported holder sizes are: • 1/4" ID × 7/16" OD • 1/8" ID × 1/4" OD

Step	Action
4	Set each holder on its platform using locating pin holes.



Visually ensure that holders are seated properly and tube slots of left and right holders are aligned. Tighten the captive screw as shown below.



Holders are coded so that the instrument automatically reads the holder type and selects the appropriate program.

Result: The instrument detects the holder and the display message indicates the holder size.

The display also shows the ***INSERT BLADE*** screen.

Step	Action
5	Optional: Change tubing type. If you want to change tubing type: • Press the ***CHANGE*** button. • Press the desired tubing type on the display. If no tubing types appear on the first screen, press the ***NEXT*** button to open the second screen. ***Note:*** *If you have already inserted the blade and wish to change the tubing type, simply remove the blade to return to the* ***INSERT BLADE*** *screen.*
6	Optional: Change tubing dimension. Use a tubing holder with the desired dimension. The tubing dimension is then automatically entered in the instrument. To change a tubing holder, see *Changing tubing holder, on page 34*.

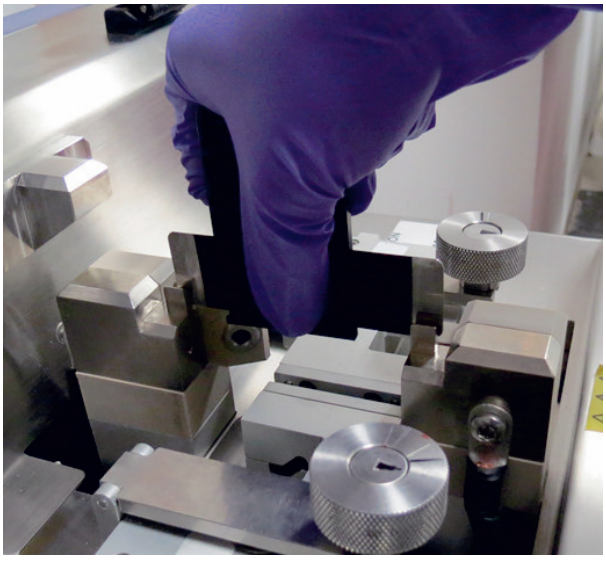
Insert a cutting blade

CAUTION

The cutting blade of STERILE TUBE FUSER - WET is a thin piece of stainless steel. It does not have a sharpened edge but can cause cuts if handled improperly. Be sure to read and understand the procedure for installing and removing the blade.

Step	Action
1	Place the STERILE TUBE FUSER - WET blade in Installation/Removal Tool as shown below.

2	Use Installation/Removal Tool to install the blade by pressing the top of the tool with the palm of the hand. During the blade installation, secure the blade within the tool by compressing with thumb as shown in the image below.



3	Press Installation/Removal Tool with palm of your hand until the blade is fully inserted into mounted position. Remove Installation/Removal Tool.

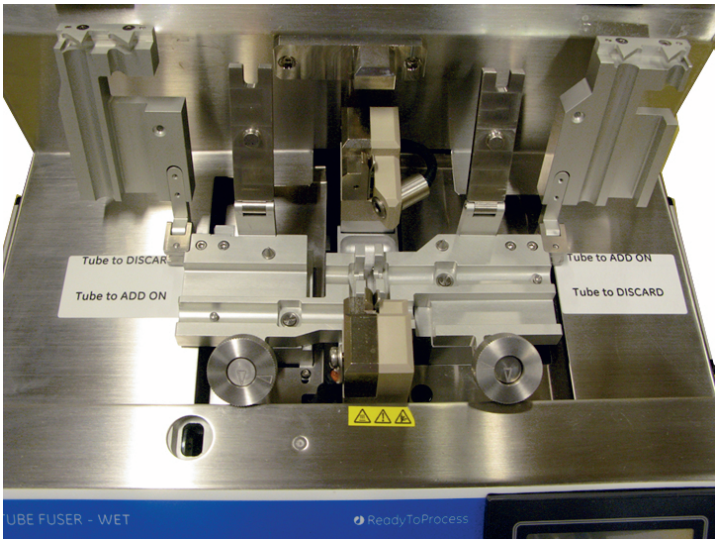
Step	Action
4	Close the STERILE TUBE FUSER - WET lid and press the Cover Lock button, for location see *Section 1.3 STERILE TUBE FUSER - WET, on page 10*. Once you press the Cover Lock button, the blade automatically retracts into the instrument.
5	Wait for the cover lock to release. *Result:* The display shows the ***INSTALL TUBING*** screen and displays the tubing dimension and type. ***Note:*** *Check that required tubing dimension and tubing type are shown.*

Note: *Always use the Installation/Removal Tool to prevent the blade from bending. Bent blades may lead to poor weld.*

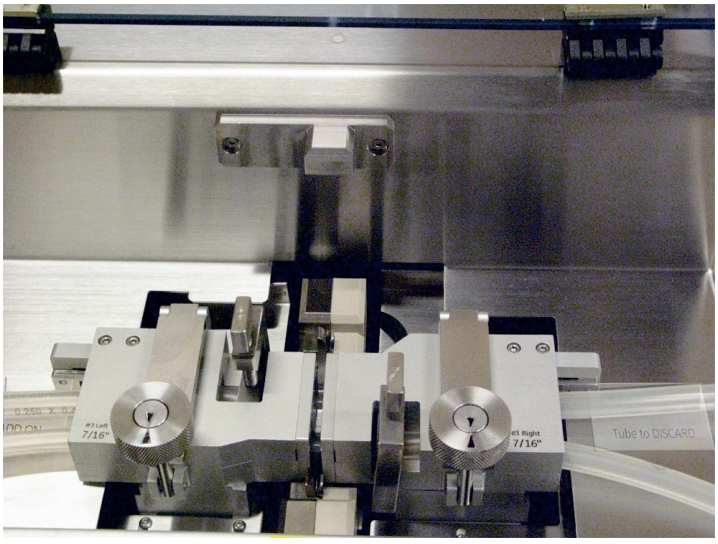
Insert tubing and start welding

Step	Action
1	Clean the outside of the fluid-filled tubing area to be connected using a suitable disinfectant. 70% ethanol or isopropyl alcohol can be used as a suitable disinfectant.
2	Unscrew the knob and move the knob shaft away from the holder.

Step	Action
3	Open the top handle and leave it fully open. Refer to image below. Open the upper holder body and turn upper holder body by 90 degrees.



4	Place the fluid-filled tubes firmly in the holders. The tubing ends must protrude out beyond each holder. Refer to *Schematic operation, on page 16* for more information.

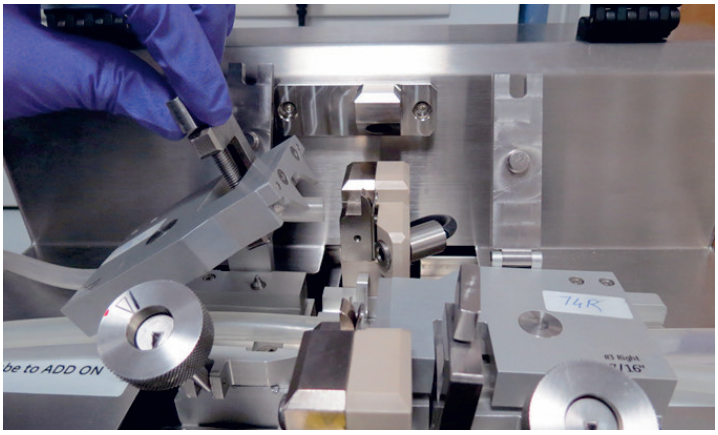


Step	Action
5	Turn the upper holder body by 90 degrees. Close the upper holder body of both right and left tube holders.
6	Press both the holders simultaneously with your fingers near the tube pinching area.
7	Close top handle of both holders.
8	Engage knob shaft with top handle. Tighten the knob until it matches the arrow indication.
9	Tighten knob on both left and right holders one by one.
10	Clamp the tubes using external tubing clamps at locations as shown in schematic operation. The instrument detects the tubes and the display shows ***READY TO CUT*** and prompts the user to close the cover. ***Note:*** *Clamp the tubes using external clamps before starting the welding operation.* *The minimum recommended distance to use external clamps on tubes to be connected is 20 mm after the tube holders.*
11	Close the cover.
12	Press and hold the Cover Lock button for a few seconds to start the program. *Result:* The instrument starts to weld the tube.

Remove fused tubing and turn off the instrument

Step	Action
1	Open the cover when the cover lock releases after the successful completion of the cycle and the display shows a ***WELD COMPLETE*** message.
2	Remove the used cutting blade with the Installation/Removal Tool. Secure the blade within the tool by squeezing with your thumb as shown in the image in Step 2 of *Insert a cutting blade, on page 27*.
3	Unscrew the knob of the left and right tube holders and move the knob shaft away from holders. Open the top handles and leave them at fully open position. Refer to image in Step 3 of *Insert tubing and start welding, on page 29*.

Step	Action
4	Hold and lift the left external clamp used on the tube to be discarded along with upper holder body.



5	Separate external clamp along with the tube to be discarded in clamped condition from the tube holder.
6	Turn upper holder body by 90 degrees.
7	Remove the tube to be discarded from the right tube holder by repeating steps 4 to 6 for the right tube holder.
8	Remove the fused tubing and visually inspect the fused tube.

Note:

If fused tubes are found joined internally, press the joint with two fingers and twist to unblock the internal joint .

Note:

Inspect the weld carefully before use, see Inspecting weld quality, on page 35.

9	Discard the cut ends.

Note:

During the cutting operation and while removing discarded tubes, small quantities of fluid might spill over. This needs to be cleaned after every usage using suitable disinfectant like 70% ethanol or isopropyl alcohol and lint free cloth.

Step	Action
10	Optional: If you want to weld different tubing size, change the tubing holder. Refer to *Changing tubing holder, on page 34* for more information. OR Switch off the power to STERILE TUBE FUSER - WET by pressing the power switch to the "**O**" position.
11	Close the cover and press the Cover Lock button to continue with next tube welding cycle. *Result :* Display shows ***INSERT BLADE*** screen. Start at step 1 of *Insert a cutting blade, on page 27*.

2.3 Changing tubing holder

Changing tubing holder

The tubing holders can be quickly changed to connect different diameter tubing. The tubing holders must be changed as a pair (left and right tubing holders must be of the same size).

The tubing holders are coded so that the instrument automatically reads the tubing holder type and selects the appropriate program.

Follow the steps below to remove and install the new holders.

Tool Required

M4 Flat screwdriver

Step	Action
1	Open the instrument's cover.
2	Open the existing holder and locate the captive screw. Loosen the captive screw using the M4 Flat screwdriver and pull the holder off the locating pins.
3	Repeat step 2 on the second holder.
4	To install the new holder, set each new holder on its platform. Align the new holders to the correct position using locating pins.
5	Tighten the captive screws.
6	Close the holder.

2.4 Inspecting weld quality

Inspecting weld quality

STERILE TUBE FUSER - WET is designed to make reproducible and reliable connections, however it is still critical to inspect the weld prior to use.

WARNING

Remove the external clamps only after confirming a good weld.

CAUTION

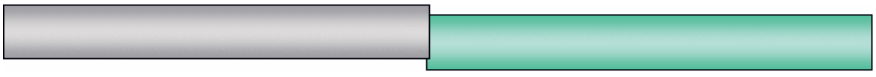
Make sure that the tubes are properly clamped with external clamps on both sides of the weld. This ensures that the sterility of the processing fluid is not compromised if any ruptures emerge during inspection. Ensure that the tubings do not come apart or start to crack.

Note: *If fused tubes have been found joined internally, press the joint with two fingers and twist gently to unblock the internal joint. Then follow the inspection method below.*

Note: *Allow the weld to cool for 2 to 3 minutes before inspection to achieve optimal strength.*

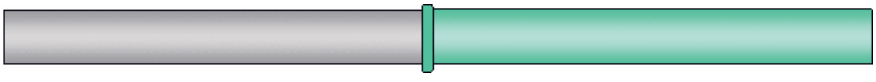
Axial alignment

Check that the tubing is axially aligned. If the tubing is offset, then the weld will be weaker on one side. Do not use such welds. Contact Service to realign the instrument.



Uniform weld

The illustration below shows an example of a correct welding with a uniform flange:



Check that you see a flange all around the weld. This indicates that the weld is uniform in the radial direction.

If you do not see a flange all the way around, then discard the weld. Check the following and weld again.

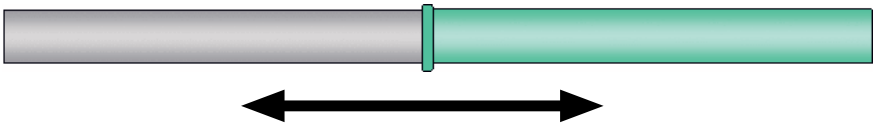
- Ensure that correct tubings are used.
- Ensure that correct holders are used.
- Ensure that approved tubing size and formulation are used.
- Insert a new blade.
- Ensure that the holders are closed and properly latched.

If you are unable to get a uniform flange, contact Service for help.

Good tensile strength

Make sure that the tubes are properly clamped on both sides of the weld in order not to compromize the sterility of the tube if any ruptures emerge. Pull gently at the weld and make a gentle twist.

The tubing should not come apart or start to crack.



2.5 Using the printer

A separate printer package can be purchased and connected to the STERILE TUBE FUSER - WET printer port located on the rear panel. To use the printer, connect the printer AC adaptor to a 100 to 240 V~, 50 or 60 Hz power supply and to the printer. Connect the supplied communication cable to the printer DB-25 connector and to the STERILE TUBE FUSER - WET connector.

The printer will print reports that includes the unit ID, program version, tube data version, the tube type and OD of the tubing being used, and the current weld number along with other relevant parameters related to the welding conditions of the particular weld being performed.

In addition to displaying the instrument setup information, the printer will also print any errors that may occur during operation. This will include the error number, a brief description of the error, and a time stamp.

3 Troubleshooting

In this chapter

Section	See page
3.1 Error checking	39
3.2 General troubleshooting and error messages	40

3.1 Error checking

STERILE TUBE FUSER - WET is designed to monitor all aspects of its operation. If a step does not perform properly, the unit will not proceed to the next step of the operation.

Step	Action
1	**Setup** The instrument checks that the holders are correctly installed and that no tubing is present. The unit goes through internal electronic diagnostics to check that all systems are functional. Finally, the holders are moved into alignment and checked. STERILE TUBE FUSER - WET uses position-sensing switches and probes to provide feedback on correct positioning.
2	**Blade Installed** The unit checks that a blade is installed. Then, the blade is retracted into the instrument.
3	**Tubing installed** The unit checks that the tubes are correctly installed in each holder and that everything is in the correct position. If all checks are satisfactory, the unit starts heating the blade to about 400°C for sterilization and depyrogenation. An infrared sensor measures the blade temperature and modulates power to control temperature. The program will fail if the measured temperature is different from the controlled temperature. After a user-set time (5 to 10 seconds), the blade is allowed to cool to a preset temperature (190°C to 270°C) depending on the tubing type and diameter. The cutting process then begins. The blade temperature is controlled at all times, and the program will fail if the temperature is not maintained. Once the tubing has been cut, the holders are moved into alignment. Position sensors verify that correct positioning has occurred. An error will occur if the holders do not move correctly. After alignment, the holders are moved towards each other to form the weld as the blade moves upwards. The amount of movement and timing is programmed and monitored by position sensors.
4	**Cool Down** The unit is then allowed to cool to a preset temperature (typically 50°C) and that is kept for additional few seconds. This ensures that the blade is safe to touch and that the weld is properly annealed. The cover interlock is then released to signal the completion of a successful weld. After the tubing and blade have been removed, press the Cover Lock button to reset the unit for the next weld.

3.2 General troubleshooting and error messages

For information about general troubleshooting and error messages, refer to the *STERILE TUBE FUSER - WET Operating Instructions*.

4 Reference information

In this chapter

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4.1 Specifications

Parameter	Value
Supply voltage	100-120 VAC or 220-240 VAC ~ 50/60 Hz
Power	100 to 240 V~ auto switching, 50 or 60 Hz, 3.3 A
Maximum current	3.3 A
Fuse specification	2 x T4.0 AL 250 V
Dimensions (W × D × H)	395 × 370 × 265 mm
Weight	16 kg
Acoustic noise level	< 70 dB A
Operating temperature	2°C to 35°C
Storage temperature	2°C to 35°C
Relative humidity tolerance	20% to 80%, non-condensing

4.2 Compatible tubing

Introduction

STERILE TUBE FUSER - WET is designed to join thermoplastic tubing.

Note: *STERILE TUBE FUSER - WET cannot be used to join silicone tubing or PTFE.*

Suitability is based on typical tubing material. The user must determine suitability of autoclaved, irradiated, or otherwise treated tubing.

Tested tubing brands

The tested tubing brands are listed in the table below.

*Denotes the factory loaded tubing types.

Tubing dimension (I.D. x O.D. in inches) Data ver: 1.0 Date: 09/11		
Tubing brand	**1/8 x 1/4**	**1/4 x 7/16**
C-FLEX™ 082*	+	+

Note: *The tubing brand names on the instrument screen may not look exactly the same as in the table above. The tubing brand names displayed on the instrument screen are abbreviations with the purpose to identify the tube material.*

4.3 Blade contact materials

The cutting blade is made of a special Nichrome alloy (NiCrA) that has the required electrical characteristics for resistance heating.

The tubing is in contact with a black polytetrafluoroethylene (PTFE) coating only. This coating is applied at high temperature and is suitable for food contact applications. The coating ensures minimal adhesion to the tubing during the welding and cutting cycle. This improves the quality of the weld and results in minimal smearing. The inert nature of the coating also eliminates any potential contamination.

The black, reflection-free coating also improves the infra-red emissivity of the blade making it possible to accurately estimate blade temperature with non-contact infrared sensors.

More information about the coating material may be required for cGMP validation. Please contact our Customer Service department and ask for non-disclosure forms.

NOTICE

Only use PTFE coated cutting blades (BLADES-IR/50) specified for use with STERILE TUBE FUSER - WET. For optimal use, do not reuse blades.

4.4 Ordering information

The table below lists details related to the ordering information.

Sl. No.	Catalog number	Description
1	28411701	STFIRC BLADES 50
2	29011931	Blade Removal Tool
3	29011782	STF-WET Holder 7/16"
4	29011837	STF-WET Holder 1/4"
5	29011018	Clamp tool Assembly-STF-WET
6	WV001984	KEY, REPLACE 6 TUMBLER

For more details on ordering information and for information about spare parts and accessories, visit www.gelifesciences.com/bioprocess or contact your local GE Healthcare representative.

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